CLAIMS

What is claimed is:

1. A heat exchange/intra-aortic counterpulsation catheter device comprising:

an elongate catheter having a proximal end and a distal end, said catheter being advancable, distal-end-first, into the aorta of a human or veterinary patient;

a counterpulsation balloon useable for effecting intra-aortic balloon counterpulsation; and

a heat exchanger useable to cool at least a portion of the patient's body to a temperature that is at least 1 °C below normothermia.

2. A device according to Claim 1 wherein the heat exchanger comprises a heat exchanger through which heat exchange fluid is circulated.

3. A device according to Claim 2 wherein said heat exchanger comprises a heat exchange balloon.

4. A device according to Claim 3 wherein the heat exchanger comprises a single-lobed heat exchange balloon.

5. A device according to Claim 3 wherein the heat exchanger comprises a multi-lobed heat exchange balloon.

6. A device according to Claim 1 wherein at least a portion of the heat exchanger is metallic.

7. A device according to Claim 3 wherein the heat exchange balloon and the counterpulsation balloon comprise a single balloon that is useable for both counterpulsation and heat exchange.

8. A device according to Claim 1 wherein the heat exchanger comprises a heat exchange surface and wherein the device further comprises a flow disruption surface associated with the heat exchange surface, the flow disruption surface being configured to disrupt the laminarity of blood flow adjacent to the heat exchange surface, thereby enhancing the efficiency by which the heat exchanger exchanges heat with the flowing blood.

9. A device according to Claim 1 wherein the counterpulsation balloon is positioned at a first location on the catheter and the heat exchanger comprises a heat exchange surface located at a second location on the catheter.

10. A device according to Claim 9 wherein the fist location is closer to the distal end of the catheter than the second location.

11. A device according to Claim 9 wherein the second location is closer to the distal end of the catheter than the first location.

12. A device according to Claim 9 wherein the heat exchanger and the counterpulsation balloon comprise a single balloon which is a) configured and useable to effect intra-aortic counterpulsation and b) receives a heat exchange medium such that heat is exchanged between the heat exchange medium and the blood, through at least a portion of the balloon.

13. A system comprising a heat exchange/intra-aortic counterpulsation catheter device according to Claim 1, further in combination with:

apparatus attachable to the catheter and useable to cause a) inflation and deflation of the counterpulsation balloon in response to the patient's cardiac cycle to effect intra-aortic balloon counterpulsation that results in a beneficial effect on the patient and b) at least cooling (and preferable cooling or heating) of the heat exchanger to cause cooling of at least a portion of the patient's body (e.g., the heart) to a temperature that is at least 1 °C below normothermia.

14. A method for treating a human or veterinary patient who suffers from congestive heart failure or another condition wherein the patients cardiac output is subnormal, said method comprising the steps of:

a. providing a heat exchange/intra-aortic counterpulsation catheter comprising i) an elongate catheter having a proximal end and a distal end, said catheter being advancable, distal-end-first, into the aorta of the patient, ii) a counterpulsation balloon useable for effecting intra-aortic balloon counterpulsation; and, a heat exchanger useable to cool at least a portion of the patient's body to a temperature that is at least 1 °C below normothermia.

b. advancing the heat exchange/intra-aortic counterpulsation catheter, distal end first, into the patient's aorta such that the counterpulsation balloon is positioned in the thoracic aorta;

c. driving and controlling the counterpulsation balloon and heat exchanger so as to effect intra-aortic balloon counterpulsation while cooling and/or maintaining the temperature of at least a portion of the patient's body to a temperature that is at least 1 °C below normothermia.

15. A method according to Claim 14 further comprising the step of:

d. administering an antishivering treatment tot he patient.

16. A method according to Claim 14, wherein the patient's body temperature is cooled to and maintained within the range of 32-34°C while intra-aortic counterpulsation is performed.

17. A method according to Claim 15 wherein the anti-shivering treatment is selected from the group of anti-shivering treatments consisting of: i) administering a therapeutically effective amount of an anti-shivering agent to the donor; ii) applying warmth to the skin of the donor and iii) administering a therapeutically effective amount of an anti-shivering agent to the donor and applying warmth to the skin of the donor.

18. A method according to Claim 15 wherein the anti-shivering treatment comprises administering to the donor a therapeutically effective amount of at least one anti-shivering agent selected from the group consisting of: i) dopamine receptor antagonists; ii) dopamine receptor agonists; iii) κ-opioid receptor agonists; iv) opioid agonist-antagonist analgesics; v) serotonin 5HT1a receptor agonists and vi) alpha-2 adrenergic receptor agonists.

19. A method for treating a human or veterinary patient who suffers from congestive heart failure or another condition wherein the patients cardiac output is subnormal, said method comprising the steps of:

a. providing a heat exchange catheter comprising i) a heat exchange catheter body and ii) at least one heat exchanger for exchanging heat with blood flowing through a blood vessel into which the heat exchange catheter body is inserted;

b. providing an intra-aortic balloon counterpulsation catheter comprising i) a counterpulsation catheter body and ii) a counterpulsation balloon useable for effecting intra-aortic balloon counterpulsation;

c. inserting the heat exchange catheter into the patient's vasculature such that blood flows in heat exchange proximity to the heat exchanger;

d. inserting the intra-aortic balloon counterpulsation catheter into the patient's vasculature such that the counterpulsation balloon is positioned within the patient's aorta;

e. using the intra-aortic balloon counterpulsation catheter to effect intra-aortic balloon counterpulsation; and,

f. using the heat exchange catheter to cool the temperature of at least a portion of the patient's body to a temperature that is at least 1 °C below normothermia.

20. A method according to Claim 19 further comprising the step of:

g. administering an antishivering treatment tot he patient.

21. A method according to Claim 20 wherein the wherein the anti-shivering treatment is selected from the group of anti-shivering treatments consisting of: i) administering a therapeutically effective amount of an anti-shivering agent to the donor; ii) applying warmth to the skin of the donor and iii) administering a therapeutically effective amount of an anti-shivering agent to the donor and applying warmth to the skin of the donor.

22. A method according to Claim 20 wherein the anti-shivering treatment comprises administering to the donor a therapeutically effective amount of at least one anti-shivering agent selected from the group consisting of: i) dopamine receptor antagonists; ii) dopamine receptor agonists; iii) κ-opioid receptor agonists; iv) opioid agonist-antagonist analgesics, v) serotonin 5HT1a receptor agonists and vi) alpha-2 adrenergic receptor agonists.

23. A method according to Claim 19, wherein the patient's body temperature is cooled to and maintained within the range of 32-34°C while intra-aortic counterpulsation is performed.

24. A method according to Claim 19 wherein the heat exchanger is positioned in a vein.

25. A method according to Claim 24 wherein the heat exchanger is positioned in the vena cava.